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From: Jeffrey A. Lindeman	Date: May 3, 2005	No. of Pages: 7 (including this page)	Client/Matter: 032034-002000

Comments:

Re: U.S. Patent App. No. 10/089,452
Filed: January 27, 2003
Inventor(s): Christian Reiter
Title: Improved Method For the Detection of Acid Resistant Microorganisms In the Stool

Attached please find:

Transmittal Sheet
Extension of Time for Five months
Response to Restriction Requirement

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/089,452
Filing Date	January 27, 2003
First Named Inventor	Christian Reiter
Group Art Unit	1645
Examiner Name	Nita M. Minnifield
Total Number of Pages in This Submission: 6	Attorney Docket Number: 032034-002000

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☒ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s)
- ☐ Declaration and Power of Attorney
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
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- ☐ Status Letter
- ☐ Application Data Sheet
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- ☒ Other Enclosure(s) *(please identify below)*:

1. **Response To Restriction Requirement**

Remarks: ☒ The Commissioner is hereby authorized to charge any additional fees required or credit any overpayments to Deposit Account No. 19-2380 for the above identified docket number.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Jeffrey A. Lindeman (Reg. No. 34,658) Nixon Peabody LLP 401 9th Street, N.W. Suite 900 Washington, D.C. 20004-2128
Signature	
Date	May 3, 2005

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/089,452 Confirmation No.: 9277
Applicant	:	Christian Reiter, *et al.*
Filed	:	January 27, 2003
TC/A.U.	:	1645
Examiner	:	Nita M. Minnifield
Docket No.	:	032034-2000
Customer No.	:	22204

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION/ELECTION REQUIREMENT

Applicant has received and carefully considered the Office Action dated November 3, 2004. By this Office Action, the Examiner has required restriction of the claims under 35 U.S.C. 121 and 372 on the grounds that the application contains inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the Office Action, Applicant hereby elects, with traverse, Group I, i.e. claims 1-42, drawn to a method for detecting infection of a mammal with an acid-resistant microorganisms. In response to the Examiner's election requirement, Applicant elects, with traverse, the species comprised of:

a) *H. pylori* as the acid-resistant microorganism;

b) catalase as the antigen;

c) the group of sequences identified in claim 19, i.e. SEQ ID. NOS. 21-23, as the group of sequences that define the heavy chain of the antibody binding a catalase epitope; and the group of sequences identified in claim 21, i.e. SEQ ID. NOS. 27-29; and

(4) SEQ ID NO. 1, as the sequence of amino acids in the variable region species for light chain and heavy chain.

Claims 1-14, 19, 21, 27-42 are believed to be readable upon the elected species.

For the reasons discussed below, Applicant submits that there is unity of invention between Groups I-IV, i.e. claims 1-54, such that the restriction requirement should be

withdrawn.

As the basis for determining that the inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1, the Examiner states:

> [The inventions listed as Groups I-IV] lack the same or corresponding technical features because the technical feature of Group I, the method of detecting infection comprising the process in claim 1, is not special in view of the method of detection and antibodies to *H. pylori* antigen disclosed in Larka et al (U.S. Patent No. 5,932,430). The technical feature of Group I is not special in that it does not define a novel contribution over the prior art; as such there is not a special technical feature and therefore Groups I-IV lack a corresponding special technical feature.

(emphasis added)

Applicant respectfully submits, however, that the special technical feature of claim 1 does, in fact, define a novel contribution over the prior art. In identifying the special technical feature of an invention, consideration must be given to the contribution that the claim, considered as a whole, makes over the prior art. Claim 1 is directed to a method for detecting an infection of a mammal with an acid-resistant microorganism, wherein (a) a stool sample of the mammal is incubated with (aa) a receptor under conditions allowing a complex formation of an antigen from the acid-resistant bacterium with the receptor; or (ab) two different receptors under conditions allowing a complex formation of an antigen from the acid-resistant bacterium with the two receptors and wherein the receptor according to (aa) or the receptors according to (ab) specifically bind(s) an antigen which show, at least with some mammals, a structure after passage through the intestine that corresponds to the native structure or the structure which a mammal produces antibodies against after being infected or immunized with the acid-resistant bacterium or an extract or lysate thereof or a protein therefrom or a fragment thereof or a synthetic peptide; and (b) wherein the formation of at least one antigen-receptor complex according to (a) is detected.

To assist the Examiner in better understanding the novelty of the claimed invention, Applicant takes this opportunity to give some explanation with regard to the receptors used in the method of the claimed invention. The method used to find the receptor of the claimed invention differs essentially from the prior art, and differs particularly from the teachings of Larka, et al. For example, as illustrated in the examples of the subject application, monoclonal antibodies, which are prepared in a usual manner, are screened based on the reactivity with samples from feces. Thus, using identified methods, those receptors are found which specifically bind antigens which have passed the intestine.

This is in contrast to the teachings of Larka et al, where polyclonal serum or monoclonal antibody are obtained and thereafter those are selected having the highest infinity to the antigen used for immunization. Thus, Larka *et al.* neither disclose the method of detection of the present invention, nor the antibodies to *H. pylori* antigen as claimed.

In essence, the inventors of the claimed invention started from the teaching of Larka et al., and found a new principle for determining acid-resistant microorganisms like *H. pylori* in feces by using a different type of receptor in the test, i.e., as defined in claim 1, a receptor that specifically binds an antigen which is found after passage through the intestine. The inventors of the claimed invention found that it is possible to reliably detect infection caused by an acid-resistant microorganism if one or two specific receptors as identified in claim 1 are used. These specific receptors bind an antigen which shows a structure after the passage through the intestine that corresponds to the native structure or the structure which a mammal produces antibodies against after being infected or immunized. In fact, the inventors have discovered that it only possible to reliably detect acid-resistant microorganisms in feces when using the receptor(s) defined in claim 1. These results are particularly surprising, as it has long been presumed by those of ordinary skill that the selection of receptors in the manner disclosed by Applicant was not possible. Since the prior art never contemplated selecting those receptors binding with antigens in feces and that the method using such receptors as well novel and inventive.

The Examiner's contention that Larka et al. discloses the special technical feature of claim 1 is, therefore, misplaced. The disclosure of Larka et al. does not contemplate the use of "one receptor" but instead expressly requires polyclonal antibodies – in other words – a multiplicity of different receptors. The polyclonal antibodies are produced by immunizing rabbits and recovering antiserum. As can be seen from example 4 of Larka et al., quantitative determinations were made with known quantities of *H. pylori* bacteria as antigen rather than on fecal specimens. A predetermined number of organisms was used in an ELISA. As can be seen from the results obtained (see Col. 6 to 7 of Larka, et al.) a test using 1 million *H. pylori* yielded an OD of 0,038, whereas an OD of 0,033 was deemed to be a negative result. The results are not very encouraging. In example 4, even when using a sample containing a predetermined number of organisms, one of four samples provides a result which is regarded as negative according to table 2. Thus, this test will not be useful for detecting an infection with *H. pylori* using fecal specimens where such a high number of intact organisms will not be expected. Unlike the method of Larka et al, the claimed

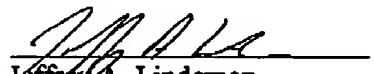
invention provides a method which is both time reliable and selective.

It should also be emphasized that Larka et al. rely on at least two different types of polyclonal antibodies ("first polyclonal antibody" and "second polyclonal antibody"). Moreover, according to Larka et al., "These problem preclude designing an assay around the use of a single antigen. They also rule out the use of monoclonal antibodies." See Larka et al., Col. 1, lines 46-48. This prevents the skilled artisan from contemplating any other protocol than that proposed by Larka et al., i.e. the use of two different types of polyclonal antibodies. Particularly, it prevents the skilled artisan from the idea of using one specific receptor specific for one antigen. Thus, Larka et al. actually teaches away from the present invention.

In view of the foregoing, Applicant submits that the special technical feature of Group I does indeed define a novel contribution over the prior art. Reconsideration and withdrawal of the restriction requirement is respectfully requested. Should the Examiner believe an interview would be of benefit in expediting the prosecution of the instant application, she is hereby invited to telephone counsel to arrange such a an interview.

Respectfully submitted,

Date: May 3, 2005



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